K011842

JAN 8 2002

510(K) SUMMARY

Manufacturer:	SLE Limited Diagnostics Group Twin Bridges Business Park 232 Selsdon Road South Croydon Surrey CR2 6PL United Kingdom
Submitted By:	Ferguson Medical Consultant to SLE
Classification Name:	Stimulator, Auditory, Evoked Response
Common/Usual Name:	Hearing Screener, Auditory Screener, Auditory Brainstem Response Screener, and others.
Proprietary Name:	SABRe Compac
Classification Number:	21 CFR 882.1900/Procode: 84 GWJ
Substantial Equivalence:	SLE SABRE ABR Screener (K993177)

Device Description: The SABRe Compac ABR Screener is an evoked potential device to be used in the diagnosis of hearing disorders.

Intended Use: The SABRe Compac Auditory Brainstem Response Screener is a device that produces a sound stimulus for use in evoked response measurements. It is intended to be used by trained professionals in the determination of hearing disorders.

Technological Characteristics: The SABRe Compac ABR device is similar in its intended use to predicate devices and existent methodologies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 8 2002

SLE Limited
c/o Frank Ferguson
Ferguson Medical
P. O. Box 12038
La Jolla, California 92039-2038

Re: K011842
Trade Name: SABRe Compac
Regulation Number: 882.1900
Regulation Name: Evoked Response Auditory Stimulator
Regulatory Class: II
Product Code: GWJ
Dated: November 25, 2001
Received: December 10, 2001

Dear Mr. Ferguson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, (Misbranding by reference to premarket notification((21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 6382041 or (301) 4436597 or at its Internet address HYPERLINK http://www.fda.gov/cdrh/dsma/dsmamain.html http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (If known): K011842

Device Name: SABRe Compac

Indications For Use:

The SABRe Compac Auditory Brainstem Response Screener is a device that produces a sound stimulus for use in evoked response measurements. It is intended to be used by trained professionals in the determination of hearing disorders.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011842

Prescription Use XX OR Over-The- Counter Use _____
(Per 21 CFR 801.109)